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(54) **Injection button and method of production thereof**

(57) A self-sealing injection button is disclosed which is adapted to be punctured by a hypodermic needle. The button is used e.g. in inflatable mammary prostheses, blood vessel restricters and during injection systems, and comprises a unitary body 12 of cured silicone rubber which has been swollen by absorption of a swelling agent, preferably a non-volatile swelling agent such as dimethylpolysiloxane fluid, and restraining means for holding the rubber to provide compressive forces therein for sealing punctures. The restraining means may be provided by a sheet of fabric, or a composite body formed by multiple layers of fabric, impregnated with the rubber. According to another possibility the restraining means is provided by a rigid ring shaped retainer. The preferred method of making the device comprises interleaving the fabric sheets with uncured silicone rubber sheets, compressing the composite to embed the fabric in the uncured rubber, curing the rubber, and then immersing the cured composite in the swelling agent.

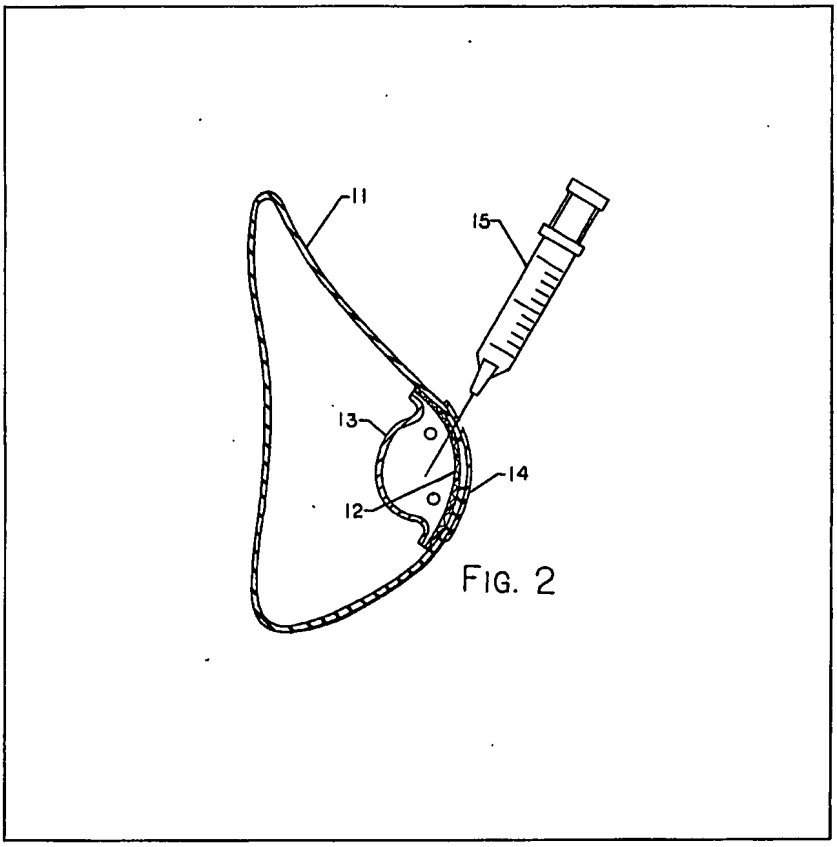

FIG. 2

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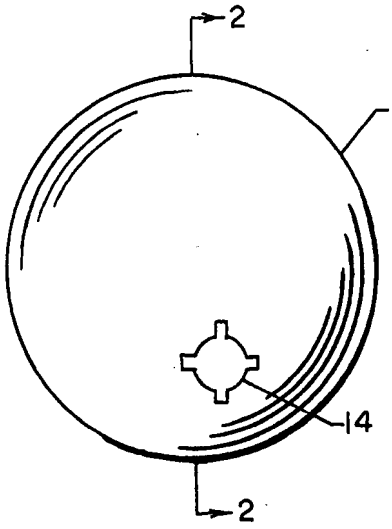

FIG. 1

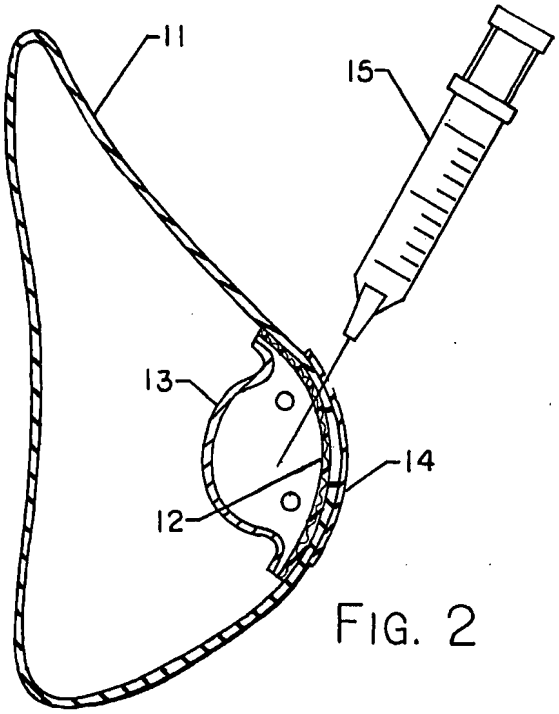

FIG. 2

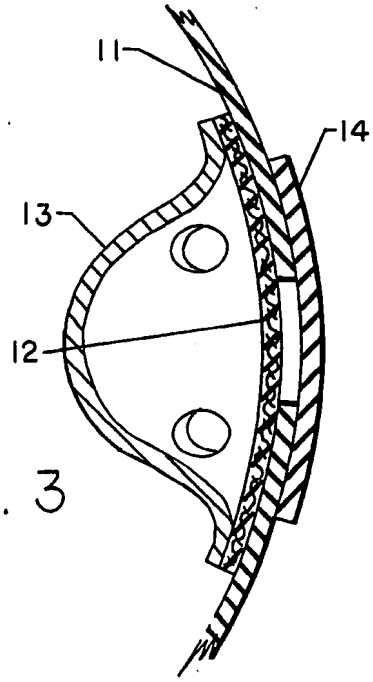

FIG. 3

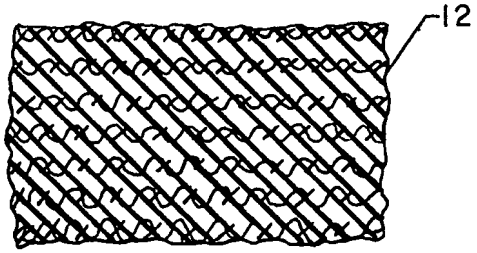

FIG. 4

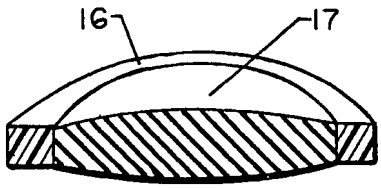

FIG. 5

SPECIFICATION

Injection button and method of production thereof

The present invention relates to an injection button and method for the production thereof. More particularly, this invention relates to self-sealing injection buttons for medical devices such as inflatable devices which are designed to be implanted in the body and then inflated *in situ*, for example, by introduction of a hypodermic needle. Such injection buttons are also usable in permanently or semi-permanently implanted devices for drug administration.

For example U.S. Patent No. 3,831,583 describes an implantable bulb designed for use with a blood vessel constricting device. In this device the injection button comprises a silicone gel-filled elastomeric bulb adapted to be pierced by a hypodermic needle for introduction of an inflating fluid. Upon withdrawal of the needle, the gel flows to seal the puncture hole.

While such devices are functional, they are relatively expensive to manufacture and there is at least some small danger of the gel being forced from the bulb in the event of extreme pressure within the device, especially if a tear should propogate in the thin rubber shell due to piercing.

Other devices designed for similar purposes have previously been described and include gels, thick soft rubber sections, or valves designed for introduction of a tubular device for introduction or withdrawal of liquid materials. Such devices are designed to be used on inflatable mammary prosthese, blood vessel restricters, and drug injection systems, for example. A need continues to exist, however, for an economical device which offers more positive sealing after puncture.

We have therefore, sought to provide an improved self-sealing injection button which provides positive sealing and is economical to manufacture. We have also sought to provide a method for making such devices.

Thus, the present invention provides a self-sealing injection button adapted to be pierced by a hypodermic needle, the injection button comprising a unitary body of cured silicone rubber swollen with a swelling agent, and restraining means for holding the rubber to provide compressive forces therein for sealing punctures.

In accordance with a preferred embodiment, the present invention comprises a unitary composite body of at least one sheet of cloth or a metal mesh fabric impregnated with cured silicone rubber swollen with a swelling agent so that the rubber provides compressive forces therein for sealing punctures made by a hypodermic needle or the like. The injection button may be produced according to the invention by a method which comprises interleaving alternate sheets of uncured silicone rubber with multiple sheets of cloth fabric, subjecting the resulting composite to pressure in order to embed the fabric in the raw silicone rubber, then curing the silicone rubber and, after curing, swelling the cured rubber by immersing it in a swelling agent such as polydimethylsiloxane fluid. If the fabric weave is such that the material is stretchable in one direction, it is necessary that the fabric sheets be rotated relative to one another, in the interleaving process so that relatively rigid restraints against fabric stretching are provided. Alternatively, restraining means other than cloth fabric may be utilized for the rubber. Alternative embodiments of the invention include use of a metal mesh fabric in place of the cloth, use of a single sheet of relatively thick cloth and use of a rigid retaining ring to confine the rubber as it is swollen.

The swelling of the rubber in the composite combined with the restraint provided by the relative rigidity of the fabric or by the ring-shaped retaining means thereby provides internal compressive forces distributed in the rubber which acts immediately to seal punctures caused by hypodermic needles or the like upon withdrawal, providing positive sealing. The fabric serves also to restrain any tendency toward tear propagation. Fabrication is a relatively simple process compared with processes required, for example, to fabricate gel-filled buttons such as those of the aforementioned U.S. Patent No. 3831583. Labour, therefore, is minimized and material costs are relatively low.

The invention will become better understood by reference to the accompanying drawings wherein:

Figure 1 is a front view in elevation of one embodiment of an inflatable mammary prosthesis made in accordance with the present invention;

Figure 2 is a cross-sectional view taken along the line 2-2 of Figure 1 and showing use of the invention with a hypodermic syringe;

Figure 3 is a fragmentary cross-sectional view of the injection area of the prosthesis shown in Figure 2;

Figure 4 is a further fragmentary view illustrating detail of the injection button shown in Figures 2 and 3; and

Figure 5 is a perspective view, partly in cross-section, of another embodiment of the invention.

Referring now to the drawings wherein like reference characters designate like or corresponding parts throughout the figures thereof, there is shown in Figures 1 and 2 an inflatable mammary prosthesis having an envelope 11 and an injection button 12 according to the present invention affixed to a portion of the envelope. As may be seen more clearly from Figure 3, a patch 14 overlies the hole in the envelope 11 which is utilized to place the injection button on the inside of the envelope.

As shown in Figures 2 and 3, a needle guard 13 is secured to the envelope 11 at a position on its interior wall underlying the injection button 12 or to the underside of the injection button. The function of the injection button 12 may be seen in Figure 2 in which a hypodermic needle 15 is shown in a position piercing the envelope and the button in inject fluid into the envelope of alternatively to remove fluid therefrom. The needle guard 13 serves to prevent accidental puncture of the back of the prosthesis envelope. The presence and shape of the needle guard, the placement of the injection button, and the precise type and shape of the prosthesis are not

essential features according to the invention and are chosen merely for illustrative purposes.

While the invention is shown for illustrative purposes in conjunction with an inflatable mammary prosthesis, it is to be understood that the invention can be used in any application wherein it is desirable to introduce or remove fluids by means such as a hypodermic needle. Such applications include, for example, skin expanders, drug infusion devices, and inflatable restriction devices such as blood vessel restricters, all of which form no part of the present invention.

Figure 3 of the drawings shows a fragmentary view of the injection button and prosthesis and Figure 4 shows a greatly enlarged cross-section of a portion of an injection button *per se*

In its preferred embodiment, the manufacturing method requires sheeted uncrued silicone rubber stock and sheets of a reinforcing fabric, which is preferably a woven open mesh polyester. The silicone rubber stock may be any of the conventional heat-curable medical grade dimethylpolysiloxane based stocks suitable for implantation in the body. The fabric chosen should be relatively non-stretchable in at least one direction. The rubber stock sheeting must have a thickness sufficient to allow total embediment of the fabric in the rubber stock, and, therefore, must have a thickness at least equal to the thickness of the fabric unless multiple sheets are used as in effect a single sheet.

In a specific embodiment, 8 sheets of Dacron (Trade Mark) polyester fabric sold under the designation 6116 by Travis Mills Corporation and which has a thickness of 0.006 inch (0.15 mm) are used with seven layers of 0.008 inch (0.20 mm) thick nonreinforced uncured silicone rubber sheeting, which may if desired incorporate a radiopaque pigment. The Dacron 6116 fabric is woven from 40 denier monofilament polyester sold by E.I. duPont deNemours and Co. under the designation Dacron type 52. A composite structure is made by interleaving the uncrued rubber sheets between the fabric sheets. Because the Dacron 6116 has a directional weave and is stretchable in one direction, multiple sheets are used and the fabric sheets are rotated relative to one another as the composite structure is being laid up to provide substantially uniform stretch characteristics in all directions.

The resulting laid up composite is placed in a chase and pressed and cured for ten minutes at 300°F. (148.89°C). The composite has the cloth fabric completely embedded in partially-cured silicone rubber. The composite is then placed in an oven to cure four hours at 350°F. (176.67°C). The cured composite is then preferably die cut into the shapes of the desired injection buttons. The die cutting exposes uncoated ends of the fabric.

The cut composite is immersed in a swelling agent to cause swelling of the rubber. While silicone rubber can be swollen with a number of liquids, a very suitable swelling medium for medical applications is polydimethylsiloxane fluid. The swelling agent must be non-volatile under atmospheric conditions if the device is to be stored for any length of time and must for medical use be biologically compatible. Polydimethylsiloxane fluid of 100 cs. viscosity at 25°C. is sufficiently nonvolatile and biologically compatible to serve the purpose. The cut ends of the fabric in the cured composite serve to help wick fluid into the material and a two week immersion has been found satisfactory. The fluid may be washed from the surfaces with solvent prior to applying adhesive to affix the injection button in place on the device on which it is to be used. Isopropanol is a suitable solvent for this purpose.

As may be seen from Figure 4, the injection button formed as described above is a composite of swollen silicone rubber and fabric. The swollen rubber, however, is under substantial compressive stress by virtue of its being held in place to large a degree by the fabric interstices. Due to the fact that the total composite is substantially nonstretchable in any direction by virtue of the rotated fabric layers, no substantial stress relief is inherent in the system. The device is designed to be punctured in use by means such as a hypodermic needle and when the needle is withdrawn the internal stresses serve to close the void instantly.

While the preferred embodiment utilizes multiple sheets of relatively thin polyester fabric in the composite, it is to be understood that single sheets of cloth or metal fabric such as stainless steel can be used as long as the material is sufficiently rigid to maintain a degree of compression in swollen rubber. As illustrated in Figure 5, a similar result can be obtained by using a rigid metallic or plastic ring 16 as the retention means for holding the rubber 17 in compression. In such instance, uncured rubber is moulded into the ring 16 and cured. The composite is then immersed in a swelling agent as heretofore described with respect to the embodiment of Figures 1-4. This embodiment, however, suffers from bulkiness and a more uneven compression distribution in the button.

CLAIMS

1. A self-sealing injection button adapted to be pierced by a hypodermic needle, the injection button comprising a unitary body of cured silicone rubber swollen with a swelling agent, and restraining means for holding the rubber to provide compressive forces therein for sealing punctures.

2. A self-sealing injection button according to claim 1, wherein the swelling agent is polydimethylsiloxane fluid.

3. A self-sealing injection button according to claim 1 or 2, wherein the restraining means comprise at least one sheet of fabric which is impregnated with the rubber.

4. A self-sealing injection button according to any of claims 1 to 3, wherein the restraining means include multiple parallel layers of fabric.

5. A self-sealing injection button according to claim 4, wherein the layers of fabric are oriented in more than one weave direction.

6. A self-sealing injection button according to claim 1 or 2, wherein the restraining means is a rigid ring surrounding the silicone rubber.

7. A method of making a self-sealing injection

button adapted to be pierced by a hypodermic needle, the method comprising

interleaving alternate sheets of uncured silicone rubber and at least one sheet of fabric to form a composite,

applying pressure to the composite to embed the fabric sheets in the uncured rubber,

curing the silicone rubber in the composite, and

swelling the cured silicone rubber by immersing it in a swelling agent to thereby provide internal compressive forces within the composite.

8. A method of making a self-sealing injection button according to claim 7, wherein adjacent layers of cloth are oriented in different weave directions as the composite is formed.

9. A method of making a self-sealing injection button according to claim 7 or 8, wherein the swelling agent is non-volatile under atmospheric conditions.

10. A method of making a self-sealing injection button according to claim 9, wherein the swelling agent is polydimethylsiloxane fluid.

11. A method of making a self-sealing injection button according to any of claims 7 to 10, which further includes, prior to swelling the cured silicone rubber, cutting the cured composite to expose edge portions of the cloth fabric to thereby enhance absorption of fluid during swelling.

12. A self-sealing injection button according to claim 1 substantially as herein described with reference to any of the accompanying drawings.

13. A method of making a self-sealing injection button according to claim 7 substantially as herein described with reference to any of the accompanying drawings.

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